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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,100	11/02/2000	Joseph Wang	37000UT9917	4989

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EXAMINER

MUTSCHLER, BRIAN L

ART UNIT	PAPER NUMBER
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1753

DATE MAILED: 10/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/705,100

Applicant(s)

WANG ET AL.

Examiner

Brian L. Mutschler

Art Unit

1753

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 May 2004 and 10 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-84 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-63 is/are allowed.
- 6) ☒ Claim(s) 64, 65 and 67-84 is/are rejected.
- 7) ☒ Claim(s) 66 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Comments

1. The rejection of claims 31 and 39-63 under 35 U.S.C. 112, second paragraph has been overcome by Applicant's amendment to the claims.
2. The rejection of claims 1-63 under 35 U.S.C. 103 over Mathies et al. as the primary reference has been overcome by Applicant's amendment to the claims. While Mathies et al. teach a first substrate having channels formed therein and a second substrate having a film electrode, the outlet of the channel does not transit the exterior edge of the substrate.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 64, 65 and 67-84 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathies et al. (WO 98/09161) in view of Wang et al. ("Performance of screen-printed carbon electrodes fabricated from different carbon inks", ELECTROCHIMICA ACTA, Vol. 43, No. 23, pp. 3459-3465 (1998)) and in view of Dubrow et al. (U.S. Pat. No. 6,251,343).

Regarding claim 64, Mathies et al. disclose an apparatus and a method of using the apparatus comprising a first substrate **11** having capillary channels formed therein,

and a second substrate (top plate) **14** bonded to the first substrate **11** (page 6, lines 2-16). Electrodes for electrochemical detection can be fabricated on the second substrate **14** (page 6, lines 25-27). Mathies et al. describe the conventional chips as having a plurality of separation channels **12** (page 6, lines 2-16; figure 1). Separations are performed by applying a potential across the channel (see figure 3). The channels comprise an inlet end and an outlet end at an edge of the first substrate (figs. 18 and 20). This rejection is supported by two different interpretations of the edge of the substrate. First, as seen in Figure 20, the outlet end of the channel **46** is formed at one edge of the substrate; being formed at an edge does not require the channel to pass through the edge of the substrate. Second, the outlet end of the channel terminates a reservoir, which forms an inner edge of the substrate (figs. 18 and 20). Therefore, the outlet end of the channel terminates at an edge of the substrate.

Regarding claims 65 and 67, Mathies et al. show the first and second substrates **11** and **14** as substantially planar and parallel (0° angle) to each other, with the second substrate bonded (sealed) to the first substrate (page 6, lines 2-31).

Regarding claims 71-73, the fluidic transport system comprises a conductive system using electrodes and a high-voltage power supply to power the electrodes and create an electrokinetic fluid transport (page 7, line 1 to page 8, line 2; fig. 23).

Regarding claim 74, Mathies et al. disclose the use of a reference electrode, electrical contacts to the electrodes and an analyte analysis system connected to the detection electrode (page 7, line 1 to page 9, line 30). The analysis system uses

amperometric detection and can use stepped or fixed potential detection (page 9, line 17 to page 10, line 32).

Regarding claims 79 and 80, Mathies et al. disclose examples providing a range of distances between the outlet end of the channel and the electrode, including distances of 20 μm , 30 μm , 300 μm and 600 μm (page 7, lines 20-25; page 11, line 11 to page 12, line 2). Mathies et al. teach that the placement of the electrode can minimize the influence of the electrophoresis voltage (page 7, lines 22-25).

Regarding claims 81-83, the detection electrode may comprise metals or carbon (page 6, lines 25-31).

Regarding claim 84, Mathies et al. disclose that conventional apparatuses have a plurality of separation channels (page 6, lines 2-16; fig. 1).

The apparatus of Mathies et al. differs from the instant invention because Mathies et al. do not disclose the following:

- a. A thick-film electrode, as recited in claim 64.
- b. The second substrate is removably positionable with respect to the first substrate, as recited in claim 64.
- c. A holder for holding the first substrate in a removably positionable position with respect to the second substrate, as recited in claim 68.
- d. The first substrate is attached to the holder and the second substrate is removably attached to the holder, as recited in claim 69.
- e. The first substrate and the second substrate are removably attached to the holder, as recited in claim 70.

- f. The thick-film electrode is a screen-printed electrode, as recited in claim 75.
- g. The thick-film electrode has a thickness from about 1 μm to about 100 μm , as recited in claim 76.
- h. The thick-film electrode has a thickness from about 8 μm to about 30 μm , as recited in claim 77.
- i. The second substrate is adjustably positionable relative to the first substrate such that the distance between the thick-film electrode and the outlet of the separation channel is variably and adjustably positionable, as recited in claim 78.

Regarding claim 64 and 75, the phrase “thick-film electrode” uses relative terminology that does not distinguish what constitutes a “thick-film” electrode. However, with regard to claim 64 and 75, Wang et al. disclose the use of “thick-film” electrodes comprising screen-printed carbon ink electrodes for microfabricated sensors and also teaches that such sensors are desirable because they are “extremely inexpensive” and are “highly reproducible electrochemical sensors” (see Abstract and Introduction).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the apparatus and method of Mathies et al. to use screen-printed, carbon ink thick-film electrodes as taught by Wang et al. because such electrodes are extremely inexpensive and highly reproducible.

Regarding claims 64, 68-70 and 78, Dubrow et al. teach that the second substrate **102** may be bonded to the first substrate **110**, or the substrates may be detachably connected using a clamping system (col. 9, lines 12-38). The clamping system can be part of the assembly or it can be separate from the substrates (col. 9, lines 31-38). When a clamping mechanism such as a clip-style clamp or screw clamp is used, both the first substrate **110** and second substrate **102** are removably attached. Furthermore, since each substrate is removable, they are also positionable to one another.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the bonded substrates in the apparatus of Mathies et al. to use a detachable connection as taught by Dubrow et al. because a detachable connection allows the cover to be removed from the substrate containing the channels.

Regarding claims 76, 77 and 80, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the electrodes and distances in the apparatus and method of Mathies et al. to use such ranges because the electrode thickness and separation distance are result effective variables that are dependent upon the electrode material and the reaction being analyzed, respectively. Different reactions and different materials all have different properties that would require an obvious variation in the operating parameters in the apparatus and method. Additionally, Mathies et al. specifically disclose that the

distance between the outlet of the channel and the electrode can minimize the influence of the electrophoresis voltage (page 7, lines 22-25).

Allowable Subject Matter

5. Claims 1-63 are allowable over the prior art of record.
6. Claim 66 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter:

Claims 1-63 are distinguished over the prior art of record by providing a microfluidic analytical device and a method for detecting an analyte having a first substrate with a separation channel and a second substrate with a thick-film electrode, wherein the outlet end of the transits an exterior edge of the first substrate and the thick-film electrode is in fluidic connection with the outlet end. Mathies et al. (WO 98/09161) teach a first substrate having a channel and a second substrate having a film electrode, but the channel does not have an outlet transiting an exterior edge of the first substrate. Ramsey et al. (U.S. Pat. No. 6,110,343) discloses an apparatus and method using a microfluidic device comprising a first substrate with a channel having an outlet that transits an exterior edge of the substrate and a second substrate overlying the first substrate (see Figures 1, 5, and 12). Although an electrode (34) is in fluid communication with the outlet, the electrode is not a thick-film electrode and is not

formed on the second substrate. The teachings of the prior art neither disclose nor suggest the combination of elements recited in the instant claims.

Claim 66 is distinguished over the prior art of record because they recite that the second substrate is perpendicular to the first substrate. In the prior art of record, the first and second substrates are parallel to one another. There is no suggestion or motivation in the prior art of record to place the second substrate perpendicular to the first substrate. Placing the second substrate perpendicular to the first substrate would allow for different positional relationships between the electrodes and the channels.

Response to Arguments

7. Applicant's arguments filed May 10, 2004, have been fully considered but they are not persuasive.

8. Regarding the rejection of claims 34, 35, and 67-84 over Mathies et al. in view of Dubrow et al., Applicant argues that a second substrate that functions as a cover "is not the function of the 'second substrate'" (see page 16 of Applicant's response). This argument is not persuasive because the function of the device does not exclude the use of the second substrate as a cover. The removable cover taught by Dubrow et al. is equivalent to the cover taught by Mathies et al. As one skilled in the art would readily appreciate, a removable cover is desirable because it allows the channels to be easily cleaned and permits the reuse of the apparatus. Since the combination of references teaches all of the limitations recited in the claims, Applicant's argument is not persuasive.

9. Applicant further argues that "at an angle" excludes a zero degree angle (see page 17). This argument is not persuasive because a zero degree angle is still an angle, which satisfies the limitations recited in the claims.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian L. Mutschler whose telephone number is (571) 272-1341. The examiner can normally be reached on Monday-Friday from 7:30am to 4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nam Nguyen can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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October 4, 2004


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